REMARKS

Claims 1-29 are pending in this application and Claims 1-29 have been rejected. In this Amendment, Claims 12-29 have been amended. Claims 1-11 have been cancelled without prejudice. No new matter has been added.

The Examiner has objected to Claims 18-29 on informal grounds. Applicant has adopted the amendments proposed in the pending Office Action. Therefore, it is requested that the objections to Claims 18-29 be withdrawn in view of the above amendments.

Claims 1-11 have been rejected under 35 U.S.C. 101 and under 35 U.S.C. 112, second paragraph. Applicant has cancelled Claims 1-11 without prejudice. It is submitted that the rejections of Claims 1-11 are now moot and it is requested that the rejections be withdrawn.

Claims 12-29 have been rejected under 35 U.S.C. 112, first paragraph, as not enabled by the specification. The Examiner has taken the position that the specification is enabling for preventing mortality or sudden death caused by the reoccurrence of a myocardial infarction. However, the Examiner has advanced that the specification does not reasonably provide enablement for preventing mortality or sudden death in general in patients who have suffered a myocardial infarction.

It is submitted that this rejection is not well taken. However, in the interest of advancing prosecution, Applicant has amended Claims 12 and 24 and it is submitted that Claims 12 and 24, as well as dependent Claims 13-17, 25, and 26 are now allowable in view of the amendments made to Claims 12 and 24.

Regarding independent Claims 18 and 27, as well as the claims depending therefrom, it is submitted that the rejection is not well taken. It is observed that these claims are directed towards the prevention of mortality caused by sudden death in a myocardial infarction survivor. It is submitted that sudden death is cardiovascular event and can be considered a "reoccurrence," which the Examiner indicated was enabled by the specification. Therefore, it is requested that the rejection against Claims 18-23 and 27-29 be withdrawn for this reason.

Finally, it is noted that clinical data supporting the claims is provided in the specification. In particular, it is noted that data is described in the paragraph bridging pages 3 and 4 of the specification. It is submitted that this paragraph reports the results of a clinical trial of four groups of patients who had previously suffered a myocardial infarction. Group 2 received a mixture of EPA ethyl ester and DHA ethyl ester according to the present invention. As the results show, there was a 20% decrease in overall mortality and roughly a 40% decrease in mortalities caused by sudden death, as compared to Group 1, the control group. Therefore, it is submitted that sufficient testing/experimental data has been provided in the specification and it is requested that the rejection be withdrawn in view of the above statements and amendments.

Claims 12-29 have been rejected under 35 U.S.C. 103(a) as obvious in view of Leaf (U.S. Patent No. 5,760,081) and the Derwent Abstract 1992-085863 ("Nippon"). It is submitted that this rejection is not well taken.

The Examiner has taken the position that Leaf teaches every aspect of the present invention with the exception of dosage amounts and oral administration. The

Examiner relies upon Nippon for the teaching of these elements. Further, the Examiner argues that the specifically claimed amounts of the present invention are merely an optimization of the invention and that one of ordinary skill could have determined these "optimum" amounts from Nippon. It is submitted that the rejection is not well taken.

First, the Examiner has argued that Col. 5, lines 21-22, of Leaf discloses that the ethyl esters of EPA and/or DHA may be used in a prophylactic treatment. Applicant submits that this section of Leaf only discloses how EPA and DHA may be obtained or isolated. Therefore, it is submitted that this basis for the rejection is not well taken.

It is also submitted that the rejection is improper because Leaf does not disclose the use of ethyl esters as a prophylactic for ventricular fibrillation, only free esters are disclosed for this use in Leaf. Additionally, Leaf only discloses intracardial injection or intravenous infusion as methods of delivery and not the oral administration form of the present invention. It is Applicant's position that Nippon does not correct the deficiencies of Leaf.

It is also noted that Leaf and Nippon are both directed to a method of treating ventricular fibrillation in patients with myocardial infarction. However, Leaf is drawn to a method for the emergency treatment of patients suffering from a heart attack or undergoing open-heart surgery. It is also noted that Nippon reports that the drug can inhibit ventricular fibrillation which frequently appears in cardiac infarction. Therefore, Leaf is not directed to a true prophylactic like the present invention. That is, Leaf does not disclose a regimented dosage scheme for use following a myocardial infarction in order to prevent reoccurrences.

Additionally, it is noted that when one examines the Japanese Patent Abstract ("Abstract") that corresponds to Nippon (copy attached), the conclusions drawn in the pending Office Action are not well taken. The Abstract reports that the purpose of the invention is to provide the patient with a more rapidly acting antiarrhymic agent and that the drug can prevent ventricular fibrillation from often occurring in myocardial infarction and cardioplegia due to arrhythmia. It is submitted that cardioplegia is an elective stopping of the heart using chemicals, selective hypothermia or electrical stimulation used by surgeons when operating on the heart.

Therefore, it is submitted that the teachings of Leaf and Nippon are directed to the use of EPA and/or DHA to rapidly treat ventricular fibrillation in patients who are having heart attacks or are undergoing heart surgery. No mention is made of providing a prophylactic against mortality in the event of further infarctions, which is an object of the present invention.

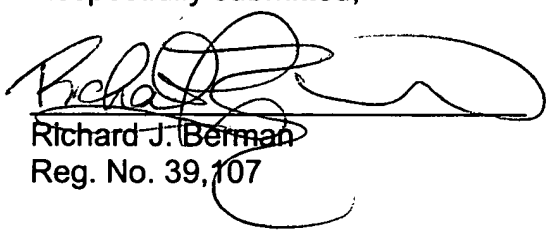
It is noted that an object of the present invention is to treat patients who have survived the hospitalization phase of acute myocardial infarction. Therefore, the present invention is directed to a long term treatment that is aimed at providing a preventative effect towards mortality caused by reoccurrence of cardiovascular events in patients who survived a myocardial infarction. This is different from the objects of Leaf and Nippon in that these references are directed only towards the immediate treatment of ventricular fibrillation. Therefore, it is submitted that the use of EPA and/or DHA for the immediate treatment of ventricular fibrillation occurring in patients having a

heart attack or undergoing heart surgery does not render the claimed invention obvious and it is requested that the rejection be withdrawn.

Should the Examiner believe anything further is desirable in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Deposit Account No. 01-2300, referring to client-matter number 101615-00012. Please charge any additional fee deficiency or credit any overpayment to Deposit Account No. 01-2300, referring to client-matter number 101615-00012.

Respectfully submitted,



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Enclosures: Japanese Patent Abstract
Petition for Extension of Time (2 Months)